

5100 Paint Branch Parkway
College Park, MD 20740-3835

M-I-03-7

May 30, 2003

TO: All Regional Food and Drug Directors
Attn: Regional Milk Specialists

FROM: Milk Safety Branch (HFS-626)

SUBJECT: Charm SL6TM Beta-lactam Test

The Food and Drug Administration's (FDA) Center for Veterinary Medicine (CVM) has evaluated data supporting the use of the Charm SL6TM Beta-lactam test for raw, commingled bovine milk.

The FDA evaluation of the data, presented by Charm Sciences, Inc., indicates that the performance of the test meets the standards established to determine the acceptance of a test for use in raw, commingled bovine milk. The acceptance of the test for raw, commingled bovine milk represents a claim for amoxicillin, ampicillin, ceftiofur, cephapirin, cloxacillin and penicillin G. These data have been evaluated in accordance with the standards established for the acceptance of screening tests for monitoring raw, commingled milk in accordance with the provisions of Appendix "N" of the Grade "A" Pasteurized Milk Ordinance.

The NCIMS Executive Board at the 2003 NCIMS Conference in Seattle, WA accepted the use of this test when used as labeled. Following is the letter of acceptance from FDA's CVM.

Copies of this memorandum are enclosed for distribution to Regional Milk Specialists, State Milk Regulatory Agencies, State Laboratory Evaluation Officers and State Milk Sanitation Rating Officers in your region. This memorandum will also be available on the FDA Web site at <http://www.cfsan.fda.gov> at a later date and should be widely distributed to State Veterinarians, State Veterinary and Pharmacy Boards, Veterinarian Professional Organizations, representatives of the dairy industry and other interested parties.

Attachment: Charm SL6™ Beta-lactam Test for Amoxicillin, Ampicillin, Ceftiofur, Ceph-
apirin, Cloxacillin and Penicillin G-Operator's Manual Validated for Raw, Commingled
Bovine Milk

/ss/

CAPT Robert F. Hennes, RS, MPH
Chief, Milk Safety Branch